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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,617	05/14/2001	Jerome B. Zeldis	9516-022	7262

20582 7590 11/17/2005

JONES DAY
51 Louisiana Aveue, N.W
WASHINGTON, DC 20001-2113

EXAMINER	
LEWIS, PATRICK T	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/853,617	ZELDIS ET AL.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 20, 2005 has been entered.

Election/Restrictions

2. Applicant's election with traverse of Group I in the reply filed on February 28, 2003 is acknowledged. The requirement was made FINAL in the Office Action dated May 19, 2003.

Applicant's Response Dated September 20, 2005

3. Claims 1-11 are pending. An action on the merits of claims 1-11 is contained herein below.

4. The rejection of claims 1-11 under 35 U.S.C. 103(a) as being unpatentable over Marx et al. Proc. Am. Soc. Clin. Onocology (1997), Vol. 18, page 454a (Marx); Pitot et al. Journal of Clinical Onocology (1997), Vol. 15, pages 2910-2919 (Pitot); and Priel et

al. US 5,622,959 (Priel) in combination is maintained for the reasons of record set forth in the Office Action dated April 20, 2005.

5. Applicant should note that the Amendment After Final dated June 24, 2005 has not been entered (see Advisory Action dated July 26, 2005). The RCE dated September 20, 2005 does not indicate that applicant wishes to have said After Final Amendment entered. Claims 61-62 are not currently pending.

Rejections of Record Set Forth in the Office Action Dated April 20, 2005

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marx et al. Proc. Am. Soc. Clin. Onocology (1997), Vol. 18, page 454a (Marx); Pitot et al. Journal of Clinical Onocology (1997), Vol. 15, pages 2910-2919 (Pitot); and Priel et al. US 5,622,959 (Priel) in combination.

Applicant's arguments filed September 20, 2005 have been fully considered but they are not persuasive. Applicant contends that there is no motivation to combine the cited references. Applicant further contends when thalidomide is co-administered with irinotecan to patients with metastic colorectal cancer, unexpected synergism occurs and a remarkable absence of gastrointestinal toxicity typically associated with irinotecan is observed. Applicant further argues that based on this showing, one of ordinary skill in the art would have reasonably extended the probative value of this result to other topoisomerase inhibitors and other types of cancers.

In response to applicant's argument that there was no motivation to combine the cited references, applicant should note that the use of materials in combination, each of which is known to function for an intended purpose, is generally held to be prima facie obvious as the idea of combining them flows logically from their having been individually taught in the prior art.

In response to applicant's argument that the co-administration of thalidomide and irinotecan to patients with colorectal cancer unexpectedly showed an absence of gastrointestinal toxicity typically associated with irinotecan, it is noted that the features upon which applicant relies (i.e., co-administration of thalidomide and irinotecan to patients with colorectal cancer) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Additionally, the instant disclosure, as filed, does not support applicant's assertion that a synergistic effect is observed when any topoisomerase inhibitor is co-administered with thalidomide in colorectal cancer treatment. The disclosures certainly does not support applicant's claim of a synergistic effect in the treatment of cancer broadly. The examiner notes the passage of Hecht cited by applicant teaching that irinotecan is generally associated with gastrointestinal toxicities; however, applicant has failed to provide a nexus or motivation as to why one of ordinary skill in the art would assume that gastrointestinal toxicities are associated with all topoisomerase inhibitors or all cancer types. Even if such a link exists, applicant has failed to provide evidence that

such gastrointestinal toxicities are reduced when a topoisomerase inhibitor other than irinotecan is used in conjunction with thalidomide. A broad claim requires a correlatively broad and sufficient disclosure to support it. Examples and description should be of sufficient scope as to justify the scope of the claims.

Conclusion

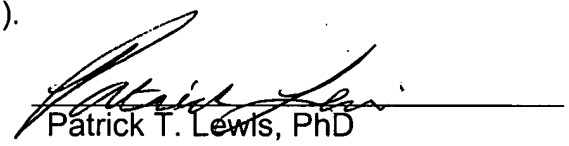
8. Claims 1-11 are pending. Claims 1-11 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patrick T. Lewis, PhD
Examiner
Art Unit 1623

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